

REMARKS

This paper responds to the Office Action mailed June 15, 2005. Claims 39-83 remain pending and under consideration in connection with the present application.

I. The Amendment to the Specification

This paper presents an amendment to the specification setting forth certain information relating to a joint research agreement that relates to the subject matter of the present invention. This amendment is permissible pursuant to 37 C.F.R. § 1.71(g). Accordingly, Applicants request entry of the amendment to the specification pursuant to 37 C.F.R. § 1.111.

II. The Rejection of Claims 39-83 under the Judicially-Created Doctrine of Obviousness-Type Double Patenting Should be Withdrawn

Claims 39-83 stand rejected under the judicially-created doctrine of obviousness-type double patenting as allegedly obvious variants of claims 1-58 of U.S. Patent No. 6,770,648 ("the '648 patent"). Further, claims 39-83 stand provisionally rejected under the same doctrine as allegedly obvious variants of claim 1 of copending U.S. Patent Application No. 10/956,251 ("the '251 application").

In response, Applicants respectfully submit that no claim of the '648 patent provides motivation to select the specific subgenus of compounds recited by claims 39-83¹. As such, the ordinarily-skilled artisan would not regard the subject matter of claims 39-83 as obvious variants of any claim of the '648 patent.

A. The Legal Standard

Under the judicially-created doctrine of obviousness-type double patenting, a claim must be patentably distinct from a *claim* of an already issued patent or pending application. *See General Food Corp. v. Studiengesellschaft Kohle mbH*, 23 U.S.P.Q.2d 1839 (Fed. Cir. 1992; emphasis added). If the claim at issue defines more than an obvious variation of the patented or pending claim, it is patentably distinct and rejection of the claim under the doctrine of obviousness-type double patenting is improper. *Id.* To establish a proper obviousness-type double patenting rejection, the Examiner must show that the claim at issue

¹ Applicants note that claims 39-49 relate to a particular genus of compounds, while claims 50-60 relate to compositions comprising such compounds and claims 61-83 relate to methods of using such compounds. Thus, the compositions and methods of claims 50-83 each recite the genus of compounds recited by claims 39-49, and thus Applicants address claims 49-83 together.

is a "mere variation" of the patented or pending claim that "would have been obvious to those of ordinary skill in the relevant art." See *In re Kaplan*, 229 U.S.P.Q. 678, 683 (Fed. Cir. 1986). In the analysis, the "patent disclosure may not be used as prior art;" instead, the Examiner must focus on the "subject matter that *has been protected*, not...something one may find to be disclosed by reading them" or the specification. See *General Food Corp.*, 23 U.S.P.Q.2d at 1846, quoting *In re Vogel*, 164 U.S.P.Q. 619, 622 (C.C.P.A. 1970) and *In re Boylan*, 157 U.S.P.Q. 370, 371 (C.C.P.A. 1968).

Moreover, a proper obviousness-type double patenting analysis parallels the obviousness analysis performed under 35 U.S.C. § 103(a). See *In re Braat*, 19 U.S.P.Q.2d 1289 (Fed. Cir. 1991) and M.P.E.P. § 804. Thus, arguments showing non-obviousness under 35 U.S.C. 103(a) may be made to show that a claim is not an obvious variant of a patented or pending claim. For example, Applicants may show that the claims at issue are not obvious variants of the patented claims by showing that such claims are not *prima facie* obvious variants of the patented claims. One way Applicants may show such non-obviousness is to show that the patented claims define a genus that does not suggest the species or subgenus recited by the claims at issue. See *In re Baird*, 29 U.S.P.Q.2d 1550 (Fed. Cir. 1994).

**B. No Claim of the '648 Patent Suggests Selection
of the Subgenus Recited by Claims 39-83**

None of the generic claims of the '648 patent suggest the subgenus of compounds recited by claims 39-83, as none of the '648 patent's claims provides the specific motivation needed to select the particular substituents recited by claims 39-83. Applicants note that the PTO has referenced Table 24 of the '648 patent as depicting compounds within the presently-claimed subgenus. While Applicants do not dispute that the presently claimed compounds are encompassed within the genera claimed by the '648 patent, Applicants respectfully remind the PTO that the specification of the '648 patent disclosure cannot be used to construct the obviousness-type double patenting rejection. Rather, only the *claims* of the '648 patent can be used in this analysis, none of which provide any motivation to select the *particular* substituents necessary to construct the particular subgenus recited by claims 39-83.

No claim of the '648 patent provides any express motivation to select the any members of the claimed subgenus of compounds from the genera defined by these claims. The '648 patent claims compounds that have PPAR γ modulatory activity, but no claim is drawn to a particular compound taught to have such PPAR γ modulatory activity. As such,

the claims of the '648 patent provide no motivation to the ordinarily-skilled artisan to select the particular substituents necessary to construct the presently-claimed subgenus of compounds from the genera defined by the '648 patent's claims. In view of this absence of suggestion or motivation, the PTO cannot establish that claims 38-83 are *prima facie* obvious variants of the claims of the '648 patent.

C. The Provisional Rejection of Claims 39-83 as Obvious Variants of Claim 1 of the '251 Application Should Be Withdrawn

Claims 39-83 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 1 of the '251 application. Without agreeing to the propriety of the rejection, Applicants believe that this provisional rejection is the last remaining issue prior to allowance of the present claims. As such, Applicants respectfully request that the provisional rejection of claims 39-83 be withdrawn, and that the issue of double patenting between the present claims and those of the '251 application be considered, if proper, during prosecution of the '251 application. See M.P.E.P. § 804 I.B.

III. The Rejection of Claims 1-45 as Obvious under 35 U.S.C. § 103(a) Should be Withdrawn

Claims 1-45 stand rejected as obvious under 35 U.S.C. § 103(a) over the '648 patent. In particular, the PTO contends that claims 39-83 are obvious over the '648 patent because the '648 patent's Table 24 suggests the specific substituents necessary to make the compounds of claims 1-45. As an initial matter, Applicants make clear for the record that they do not agree with the propriety of the rejection and do not concede that the PTO has established *prima facie* obviousness of the instant claims over the cited references. Nonetheless, even assuming *arguendo* that the rejected claims are *prima facie* obvious over the combination of the cited references, the rejection should be withdrawn because the '648 patent is not prior art as set forth in 35 U.S.C. § 103(c)(2). See also 37 C.F.R. §§ 1.71(g) and 1.104.

Section 103(c) provides, in part, that a reference that qualifies as prior art only under § 102(c), (f), or (g) can be removed for the purposes of obviousness if the subject matter described in the reference was subject to an obligation to assign to one or more parties to a joint research agreement under certain circumstances. These circumstances are present if the following three factors are met with relation to the presently claimed invention:

(1) the claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the invention was made;

(2) the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and

(3) the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement. See 35 U.S.C. § 103(c)(2).

The invention claimed in the '648 patent, when made, was subject to an obligation to assign to Tularik Inc. (the predecessor-in-interest to Amgen Inc.; hereinafter "Tularik"), and the '648 patent was in fact assigned to Tularik. The assignment from the inventors to Tularik was recorded at Reel 015886, Frame 0253. As noted by the PTO, the '648 patent qualifies as prior art to the present application, if at all, only under 35 U.S.C. § 102(e).

As evidenced by the Statements by both of the Assignees of the present application filed herewith, the invention claimed in the present application was made by parties to and as a result of activities undertaken within the scope of a Joint Research Agreement between Tularik and Japan Tobacco, Inc. By operation of the terms of the agreement, the invention claimed in the present application was subject to an obligation to assign to Tularik and Japan Tobacco, Inc. at the time the invention was made.

Accordingly, the '648 patent claims an invention that was subject to an obligation to assign to a party to a Joint Research Agreement within the meaning of 35 U.S.C. § 103(c)(3). The present application claims an invention that was made pursuant to the Joint Research Agreement as a result of activities within the scope of the Joint Research Agreement.

Further, the present paper presents an amendment to the specification setting forth the parties to the Joint Research Agreement, the date of its execution, and a concise statement of the field of the claimed invention, as required by 37 C.F.R. § 1.71(g).

Applicants believe that all requirements for removing the '648 patent as prior art to the present application pursuant to 35 U.S.C. § 103(c) and 37 C.F.R. § 1.71(g) have been met. Further, Applicants respectfully submit that without the '648 patent, the PTO cannot establish *prima facie* obviousness of the presently claimed invention. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 39-83 as obvious under 35 U.S.C. § 103(a) over the '648 patent.

CONCLUSION

In light of the above amendments and remarks, Applicants respectfully request that the Examiner reconsider this application with a view towards allowance.

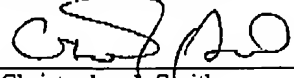
Applicants believe that no fee is due in connection with this response beyond the fees associated with the Petition for Extension of Time. Should an additional fee be required, the

Commissioner is hereby authorized to charge any such required fee(s) to 01-0519. Two copies of fee transmittal are enclosed for such purpose.

Date:

12/9/05

Respectfully submitted,



Christopher J. Smith
Reg. No. 40,179
AMGEN INC

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	McGee et al.	Confirmation No.:	1490
Serial No.:	10/719,997	Art Unit:	1625
Filed:	November 20, 2003	Examiner:	Seaman, D. Margaret
For:	Quinoliny and Benzothiazoylyl Modulators	Attorney Docket No.:	018781-006330US T00-014-3/US

STATEMENT UNDER 35 U.S.C. § 103(C)(2)

The undersigned assignee of an undivided interest in the above-identified subject application hereby states:

- 1) the invention claimed in the above-identified subject application was made on behalf of Tularik Inc. (predecessor in interest to Amgen Inc.; hereinafter referred to as "Tularik"), and Japan Tobacco, Inc. (hereinafter "Japan Tobacco"), at the time said invention was made;
- 2) based upon information and belief, the invention claimed in U.S. Patent No. 6,770,648 was made on behalf of Tularik, at the time said invention was made;
- 3) Tularik and Japan Tobacco were each parties to a Joint Research Agreement within the meaning of 35 U.S.C. § 103(c)(3) at the time the invention claimed in the above-identified subject application was made; and
- 4) the invention claimed in the above-identified subject application was made as a result of activities undertaken within the scope of said Joint Research Agreement.

Further, Japan Tobacco states that it is the Assignee of an undivided right, title, and interest in the above-identified subject application by virtue of a chain of title from the inventors of the claimed subject matter as shown below:

An Assignment of U.S. Application No. 09/894,980, the parent to the present application, from Atsushi Hagiwara, Noburu Furukawa, and Hisashi Shinkai to Japan Tobacco was executed September 28, 2001, September 28, 2001, and August 10, 2001, respectively, and recorded October 9, 2001, at Reel 012246, Frame 0338.

The undersigned, the [Title] of Japan Tobacco, hereby states that he is authorized to act on behalf of Japan Tobacco, the Assignee of an undivided right, title, and interest in the above-identified subject application.

Date:

Dec. 1, 2005

[Name of Signer] Yoshinori INUBUSHI
[Title] Vice President, Intellectual Property
Japan Tobacco, Inc.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	McGee et al.	Confirmation No.:	1490
Serial No.:	10/719,997	Art Unit:	1625
Filed:	November 20, 2003	Examiner:	Seaman, D. Margaret
For:	QuinolinyI and BenzothiazoyI Modulators	Attorney Docket No.:	018781-006330US

STATEMENT UNDER 35 U.S.C. § 103(C)(2)

The undersigned assignee of an undivided interest in the above-identified subject application hereby states:

- 1) the invention claimed in the above-identified subject application was made on behalf of Tularik Inc. (the predecessor in interest to Amgen Inc; hereinafter "Tularik"), and Japan Tobacco, Inc. (hereinafter "Japan Tobacco"), at the time said invention was made;
- 2) the invention claimed in U.S. Patent No. 6,770,648 was made on behalf of Tularik at the time said invention was made;
- 3) Tularik and Japan Tobacco were each parties to a Joint Research Agreement within the meaning of 35 U.S.C. § 103(c)(3) at the time the invention claimed in the above-identified subject application was made; and
- 4) the invention claimed in the above-identified subject application was made as a result of activities undertaken within the scope of said Joint Research Agreement.

Further, Amgen Inc, states that it is the Assignee of an undivided right, title, and interest in the above-identified subject application by virtue of a chain of title from the inventors of the claimed subject matter as shown below:

An Assignment of U.S. Application No. 09/894,980, the parent to the present application, from Lawrence R. McGee, Jonathan B. Houze, and Steven M. Rubenstein to Tularik Inc., was executed September 20, 2001, September 24, 2001, and September 25, 2001, respectively, and recorded October 9, 2001, at Recd 012246, Frame 0329.

T00-014-3US

Tularik Inc., merged into Arrow Acquisition, LLC on August 13, 2004; a copy of the Certificate of Merger issued by the Secretary of the State of Delaware evidencing this merger is attached hereto.

Arrow Acquisition, LLC was renamed Amgen SF, LLC on Aug 13, 2004; a copy of the Certificate of Merger issued by the Secretary of the State of Delaware evidencing this merger is attached hereto.

An Assignment of U.S. Application No. 10/719,997 from Amgen SF, LLC to Amgen Inc was executed on Nov 7, 2005; a copy of the Assignment is attached hereto.

The undersigned, the Vice President, Law of Amgen Inc, hereby states that he is authorized to act on behalf of Amgen Inc, the Assignee of an undivided right, title, and interest in the above-identified subject application.



Date:

12/7/05

Stuart L. Watt
Vice President, Law
Amgen Inc

T00-014-3US

Delaware

PAGE 1

The First State

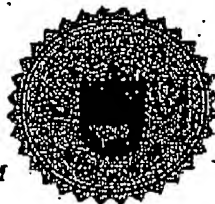
I, HARRIET SMITH WINDSOR, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF MERGER, WHICH MERGES:

"TULARIK INC.", A DELAWARE CORPORATION,

WITH AND INTO "ARROW ACQUISITION, LLC" UNDER THE NAME OF "ARROW ACQUISITION, LLC", A LIMITED LIABILITY COMPANY ORGANIZED AND EXISTING UNDER THE LAWS OF THE STATE OF DELAWARE, AS RECEIVED AND FILED IN THIS OFFICE THE THIRTEENTH DAY OF AUGUST, A.D. 2004, AT 10:34 O'CLOCK A.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF MERGER IS THE THIRTEENTH DAY OF AUGUST, A.D. 2004, AT 5 O'CLOCK P.M.

A FILED COPY OF THIS CERTIFICATE HAS BEEN FORWARDED TO THE KENT COUNTY RECORDER OF DEEDS.



3780036 8100M

040593536

Harriet Smith Windsor

Harriet Smith Windsor, Secretary of State

AUTHENTICATION: 3293954

DATE: 08-13-04

State of Delaware
Secretary of State
Division of Corporations
Delivered 10:34 AM 08/13/2004
FILED 10:34 AM 08/13/2004
SRV 040593536 - 3780036 FILE

**CERTIFICATE OF MERGER
OF
TULARIK INC.
WITH AND INTO
ARROW ACQUISITION, LLC**

Pursuant to Title 8, Section 264(c) of the Delaware General Corporation Law and Title 6, Section 18-209 of the Limited Liability Company Act, the undersigned limited liability company formed and existing under and by virtue of the Delaware Limited Liability Company Act does hereby certify:

1. The constituent business entities participating in the merger herein certified are:
 - (i) Tularik Inc., a Delaware corporation; and
 - (ii) Arrow Acquisition, LLC, a Delaware limited liability company.
2. The Agreement and Plan of Merger (the "Agreement and Plan of Merger"), dated as of March 28, 2004, by and among Amgen Inc., a Delaware corporation, Arrow Acquisition, LLC and Tularik Inc., has been approved, adopted, certified, executed, and acknowledged by each of the aforesaid constituent entities in accordance with the provisions of subsection (b) of Section 18-209 of the Delaware Limited Liability Company Act and in accordance with the provisions of subsection (c) of Section 264 of the General Corporation Law of the State of Delaware.
3. The name of the surviving limited liability company in the merger herein certified is Arrow Acquisition, LLC.
4. The Certificate of Formation of Arrow Acquisition, LLC, a Delaware limited liability company, as filed with the Secretary of State of Delaware on March 22, 2004, and as now in force and effect, shall continue to be the Certificate of Formation of said surviving limited liability company until amended and changed pursuant to the provisions of the Delaware Limited Liability Company Act.
5. The executed Agreement and Plan of Merger is on file at the principal place of business of the aforesaid surviving limited liability company, the address of which is as follows: One Amgen Center Drive, Thousand Oaks, California 91320-1799.
6. A copy of the aforesaid Agreement and Plan of Merger will be furnished by the aforesaid surviving limited liability company, on request, and without cost, to any stockholder of the constituent Delaware corporation or any member of the constituent surviving limited liability company.
7. The effective time and date of the merger shall be 5:00 p.m. (Eastern Time) on August 13, 2004.

OC679079.5

BEST AVAILABLE COPY

IN WITNESS WHEREOF, said limited liability company has caused this certificate to be signed by an authorized person, this 13th day of August, 2004.

ARROW ACQUISITION, LLC,
a Delaware limited liability company

By: 

Name: David J. Scott
Vice President and Secretary

OC679079.4

RECEIVED
ARROW ACQUISITION, LLC
12/9/2005

Delaware

PAGE 1

The First State

I, HARRIET SMITH WINDSOR, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE RESTATED CERTIFICATE OF "ARROW ACQUISITION, LLC"; CHANGING ITS NAME FROM "ARROW ACQUISITION, LLC" TO "AMGEN SF, LLC", FILED IN THIS OFFICE ON THE THIRTEENTH DAY OF AUGUST, A.D. 2004, AT 11:11 O'CLOCK A.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID RESTATED CERTIFICATE IS THE THIRTEENTH DAY OF AUGUST, A.D. 2004, AT 5:01 O'CLOCK P.M.



3780036 8100
040593762

Harriet Smith Windsor
Harriet Smith Windsor, Secretary of State

AUTHENTICATION: 3294065

DATE: 08-13-04

BEST AVAILABLE COPY

**AMENDED AND RESTATED CERTIFICATE OF FORMATION
OF
ARROW ACQUISITION, LLC**

August 13, 2004

1. This Amended and Restated Certificate of Formation of Arrow Acquisition, LLC is being duly executed and filed by David J. Scott, as an authorized person, pursuant to Section 18-208 of the Delaware Limited Liability Company Act, to amend and restate the Certificate of Formation of Arrow Acquisition, LLC originally filed on March 22, 2004.

2. The Certificate of Formation of the limited liability company is hereby amended and restated in its entirety to read as follows:

FIRST. The name of the limited liability company is Amgen SF, LLC.

SECOND. The address of the registered office and the name and the address of the registered agent of the limited liability company required to be maintained by Section 18-104 of the Delaware Limited Liability Company Act are National Registered Agents, Inc., 9 East Lookerman Street, Suite 1B, Dover, Kent County, Delaware 19901."


3. The effective date and time of this Amended and Restated Certificate of Formation shall be August 13, 2004 at 5:01 p.m. Eastern Time.

[Signature Page Follows]

OC684843.1

State of Delaware
Secretary of State
Division of Corporations
Delivered 11:11 AM 08/13/2004
FILED 11:11 AM 08/13/2004
SRV 040593762 - 3780036 FILE

IN WITNESS WHEREOF, the undersigned has executed this Amended and Restated
Certificate of Formation as of the date first above written.



David J. Scott
Authorized Person

OC684843.1

BEST AVAILABLE COPY

ASSIGNMENT

WHEREAS, AMGEN SF, LLC (hereinafter "ASF"), a limited liability company incorporated under the laws of the State of Delaware, United States of America, and having a principal place of business at 1120 Veterans Boulevard, South San Francisco, California 94080, is the assignee of interest of the inventions set forth in U.S. and foreign patents and U.S. and foreign patent applications, listed on Appendix A hereto (collectively, the "Patent Documents");

WHEREAS, AMGEN INC. (hereinafter "AMGEN"), a corporation organized under the laws of the State of Delaware, United States of America, and having a principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799, is desirous of acquiring all title, right and interest in to and under said inventions and Patent Documents;

NOW, THEREFORE, be it known to all whom it may concern;

THAT for good and valuable consideration the receipt of which is hereby acknowledged, ASF has and does hereby sell, assign, transfer and set over unto AMGEN, its successors and assigns, the full and exclusive right, title and interest including all rights acquired in foreign countries, in to and under said Patent Documents, including any divisions, renewals, continuations in whole or in part, substitutions, conversions, reissues, prolongations or extensions thereof, and in and to any and all letters patents to be granted and issued therefor, not only for, to and in the United States of America, its territories and possessions, but for, to and in all other countries and regions; and it has been and is hereby authorized and requested that the appropriate government agencies issue said letters patents to AMGEN, in accordance with this assignment.

THIS 7th day of November 2005.

AMGEN SF, LLC. (Assignor)

AMGEN INC. (Assignee)

By: Stuart L. Watt

Name: Stuart L. Watt
Title: Vice President,
Law and Intellectual Property

By: Stuart L. Watt

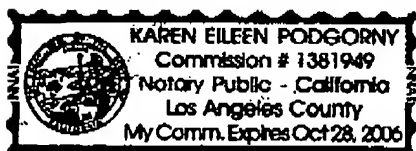
Name: Stuart L. Watt
Title: Vice President, Law

STATE OF CALIFORNIA)

COUNTY OF VENTURA)

On 7th day of November 2005, before me personally appeared Stuart L. Watt, known to me to be the person whose name is subscribed to the within instrument and acknowledged to me that he executed the same in his authorized capacity, and that by his signature on the instrument the entity upon behalf of which the person acted, executed the instrument.

WITNESS my hand and official seal.



Karen Podgorny
Name: Karen Podgorny
Notary Public

T00-014 series

APPENDIX A

<u>Country</u>	<u>Appl. No.</u>	<u>Appl. Date</u>	<u>Patent No.</u>	<u>Date of Grant</u>
US	60/214,810	Jun 26 2000		
US	09/894,980	Jun 27 2001	6,583,157	Jun 24 2003
AU	2001271837	Jun 27 2001		
BR	0112115-4	Jun 27 2001		
CA	2412723	Jun 27 2001		
CN	01812017.2	Jun 27 2001		
CZ	PV2002-4197	Jun 27 2001		
EA	200300078	Jun 27 2001		
EP	01950669.0	Jun 27 2001		
HK	03104574.3	Jun 27 2001		
HU	P0301482	Jun 27 2001		
IL	153,461	Jun 27 2001		
IN	2002/01890/MUM	Jun 27 2001		
JP	2002-605381	Jun 27 2001		
KR	2002-7017827	Jun 27 2001		

APPENDIX A

<u>Country</u>	<u>Appln. No.</u>	<u>Appln. Date</u>	<u>Patent No.</u>	<u>Date of Grant</u>
MX	PA/a/2002/012708	Jun 27 2001		
NO	20028156	Jun 27 2001		
NZ	523229	Jun 27 2001	523229	Feb 10 2006
PL	P-359996	Jun 27 2001		
SG	200207767-6	Jun 27 2001		
SK	PV1835-2002	Jun 27 2001		
TR	2002/02750	Jun 27 2001		
ZA	2002/10283	Jun 27 2001		
US	10/278,851	Oct 21 2002		
US	10/719,997	Nov 20 2003		